

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

JOHNSON MATTHEY INC.

vs.

NOVEN PHARMACEUTICALS, INC.,
SHIRE US INC., and SHIRE
PHARMACEUTICALS IRELAND
LIMITED

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CASE NO. 2:07-CV-260-CE

MEMORANDUM OPINION AND ORDER

I. Introduction

In this case, the plaintiff, Johnson Matthey Inc. (“JM”), contends that the defendants, Noven Pharmaceuticals, Inc. (“Noven”), Shire US Inc., and Shire Pharmaceuticals Ireland Limited (“Shire”) (collectively, “defendants”), infringe claims 1 and 2 of United States Patent No. 6,096,760 (“the ‘760 patent”). This memorandum addresses the parties’ various claim construction disputes. The memorandum will first briefly address the technology at issue in the case and then turn to the merits of the claim construction issues.

II. Background of the Technology

A. Methylphenidate (methyl α -phenyl-2-piperidine acetate)

The technology at issue in this case concerns two forms of methylphenidate, methylphenidate hydrochloride and methylphenidate free base. Methylphenidate hydrochloride is the salt form of the methylphenidate compound. It was discovered in 1944 and patented in 1958. *See* U.S. Patent No. 2,838,519. It “exerts a mild stimulating effect on the central nervous system, and can be used to overcome states of fatigue, depression and exhaustion, for instance in convalescence.” ‘760 Patent, col. 1, l. 14. Since 1961, methylphenidate hydrochloride, sold

under the name Ritalin™, has been used to treat Attention Deficit/Hyperactivity Disorders (“ADHD”). Because of the hydrophilic nature of methylphenidate hydrochloride, Ritalin™ is taken orally—it is unsuitable for topical administration because it is incapable of being delivered through the skin in therapeutically effective amounts.

B. The ‘760 Patent

The ‘760 patent claims methylphenidate free base. Although methylphenidate free base in oil form was first described in a patent in 1950, the ‘760 patent describes methylphenidate free base in solid form. The basic form, as opposed to its hydrophilic counterpart, is hydrophobic and adaptable for transdermal use.

JM first filed a British patent application on May 30, 1997, claiming the invention disclosed in the ‘760 patent. *See* United Kingdom Patent Application No. 9711032. JM filed the corresponding United States application on May 29, 1998, which ultimately matured into the ‘760 patent. *See* U.S. Patent Application No. 09/086,727. The ‘760 patent claims priority to the British application. As originally filed, claim 1 disclosed the following:

1. A compound comprising methyl α -phenyl-2-piperidine acetate free base, in solid form.

On May 14, 1999, the United States Patent and Trademark Office (“USPTO”) rejected claim 1 as obvious by a number of prior art references, including the Ninth Edition of the Merck Index (“Merck Index”). *See* Ex. AA to Shire’s Brief at 62-64. In response to this rejection, JM amended claim 1.¹ On October 26, 1999, the USPTO again rejected claim 1 as rendered obvious by the Merck Index. *See id.* at 79-80. In both instances, the examiner rejected the claims as obvious in part based on the disclosure in the Merck Index of methylphenidate free base in solid form with a melting point of 74° C - 75° C. *See id.* at 62-64, 79-80. In response to the second

¹ JM amended claim 1 as follows: “1. The A compound comprising methyl α -phenyl-2-piperidine acetate free base, in solid form.” *Id.* at 71.

rejection, the patentee explained to the USPTO that the melting point disclosure in the Merck Index was erroneous; Merck had recognized the error; and Merck had since removed the reference to methylphenidate free base in solid form in its Twelfth Edition of the Index. *See id.* at 88-90. The patentee also amended claim 1 for a second time. In pertinent part to support the amendment, the patentee suggested as follows:

While the Merck reference is not believed to be suggestive of the applicant's invention for reasons detailed below, it is proposed to amend claim 1 to recite the melting point of the applicant's compound in order to emphasize the uniqueness of the compound.

The examiner will appreciate that the proposed amendment of claim 1 to recite the melting point of the applicant's compound serves to highlight the unobviousness of the compound over the erroneous Merck disclosure. *Id.* at 88-89.

The examiner allowed the amended claim, stating as follows:

Applicants have provided evidence that the Merck Index 12eds has corrected the error made in the 9th edition, thus, no solid form of the free base was prepared. Since it was evidenced in the art that solid form of the free base for α -phenyl-2-piperidine acetate was not available the unexpected procedure to produce a solid form rendered the claims neither anticipated nor obvious over the art of record. *See id.* at 98.

As finally amended and issued, claims 1 and 2 of the '760 patent read as follows:

1. The compound α -phenyl-2-piperidine acetate free base, in solid form and having a melting point of 41-42° C.
2. The compound of claim 1, in crystalline form.

In this case, JM accuses the defendants of infringing claims 1 and 2 of the '760 patent. The accused drug in this case, Daytrana®, is the first and only transdermal patch to be approved for use in treating ADHD. It is manufactured by Noven and marketed by Shire. There is no dispute that Daytrana® contains methylphenidate in free base form.

III. Discussion

A. General Principles Governing Claim Construction

“A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention.” *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999). Claim construction is an issue of law for the court to decide. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996).

To ascertain the meaning of claims, the court looks to three primary sources: the claims, the specification, and the prosecution history. *Markman*, 52 F.3d at 979. Under the patent law, the specification must contain a written description of the invention that enables one of ordinary skill in the art to make and use the invention. A patent’s claims must be read in view of the specification of which they are a part. *Id.* For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. *Id.* “One purpose for examining the specification is to determine if the patentee has limited the scope of the claims.” *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed. Cir. 2000).

Nonetheless, it is the function of the claims, not the specification, to set forth the limits of the patentee’s claims. Otherwise, there would be no need for claims. *SRI Int’l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc). The patentee is free to be his own lexicographer, but any special definition given to a word must be clearly set forth in the specification. *Intellicall, Inc. v. Phonometrics*, 952 F.2d 1384, 1388 (Fed. Cir. 1992). And, although the specification may indicate that certain embodiments are preferred, particular embodiments appearing in the specification will not be read into the claims when the claim

language is broader than the embodiments. *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994).

This court's claim construction decision must be informed by the Federal Circuit's decision in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)(en banc). In *Phillips*, the court set forth several guideposts that courts should follow when construing claims. In particular, the court reiterated that "the *claims* of a patent define the invention to which the patentee is entitled the right to exclude." *Id.* at 1312 (emphasis added)(quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). To that end, the words used in a claim are generally given their ordinary and customary meaning. *Id.* The ordinary and customary meaning of a claim term "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1313. This principle of patent law flows naturally from the recognition that inventors are usually persons who are skilled in the field of the invention. The patent is addressed to and intended to be read by others skilled in the particular art. *Id.*

The primacy of claim terms notwithstanding, *Phillips* made clear that "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* Although the claims themselves may provide guidance as to the meaning of particular terms, those terms are part of "a fully integrated written instrument." *Id.* at 1315 (quoting *Markman*, 52 F.3d at 978). Thus, the *Phillips* court emphasized the specification as being the primary basis for construing the claims. *Id.* at 1314-17. As the Supreme Court stated long ago, "in case of doubt or ambiguity it is proper in all cases to refer back to the descriptive

portions of the specification to aid in solving the doubt or in ascertaining the true intent and meaning of the language employed in the claims.” *Bates v. Coe*, 98 U.S. 31, 38 (1878). In addressing the role of the specification, the *Phillips* court quoted with approval its earlier observations from *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998):

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.

Consequently, *Phillips* emphasized the important role the specification plays in the claim construction process.

The prosecution history also continues to play an important role in claim interpretation. The prosecution history helps to demonstrate how the inventor and the PTO understood the patent. *Phillips*, 415 F.3d at 1317. Because the file history, however, “represents an ongoing negotiation between the PTO and the applicant,” it may lack the clarity of the specification and thus be less useful in claim construction proceedings. *Id.* Nevertheless, the prosecution history is intrinsic evidence. That evidence is relevant to the determination of how the inventor understood the invention and whether the inventor limited the invention during prosecution by narrowing the scope of the claims.

Phillips rejected any claim construction approach that sacrificed the intrinsic record in favor of extrinsic evidence, such as dictionary definitions or expert testimony. The *en banc* court condemned the suggestion made by *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002), that a court should discern the ordinary meaning of the claim terms (through dictionaries or otherwise) before resorting to the specification for certain limited purposes. *Id.* at

1319-24. The approach suggested by *Tex. Digital*—the assignment of a limited role to the specification—was rejected as inconsistent with decisions holding the specification to be the best guide to the meaning of a disputed term. *Id.* at 1320-21. According to *Phillips*, reliance on dictionary definitions at the expense of the specification had the effect of “focus[ing] the inquiry on the abstract meaning of words rather than on the meaning of the claim terms within the context of the patent.” *Id.* at 1321. *Phillips* emphasized that the patent system is based on the proposition that the claims cover only the invented subject matter. *Id.* What is described in the claims flows from the statutory requirement imposed on the patentee to describe and particularly claim what he or she has invented. *Id.* The definitions found in dictionaries, however, often flow from the editors’ objective of assembling all of the possible definitions for a word. *Id.* at 1321-22.

Phillips does not preclude all uses of dictionaries in claim construction proceedings. Instead, the court assigned dictionaries a role subordinate to the intrinsic record. In doing so, the court emphasized that claim construction issues are not resolved by any magic formula. The court did not impose any particular sequence of steps for a court to follow when it considers disputed claim language. *Id.* at 1323-25. Rather, *Phillips* held that a court must attach the appropriate weight to the intrinsic sources offered in support of a proposed claim construction, bearing in mind the general rule that the claims measure the scope of the patent grant. The court now turns to a discussion of the disputed claim terms.

B. “having a melting point of 41 - 42° C”

The only phrase that the parties present for construction in this case is “having a melting point of 41 - 42° C.” JM proposes dividing the phrase and construing “having a melting point” and “41 - 42° C” separately, while the defendants propose construing the phrase as a whole. For

brevity, the court will define the phrase as a whole. Shire and Noven generally agree on their proposed construction, with the exception that Shire wishes to further limit the testing apparatus for determining melting point to “a capillary melting point apparatus.”

Claim Phrase	JM’s Proposed Construction	Noven’s Proposed Construction	Shire’s Proposed Construction
“having a melting point of 41 - 42° C”	<p>melting point: “Temperatures at which melting activity is taking place, ranging from the temperature at which the first sign of liquification appears to the temperature at which the material is completely liquefied.”</p> <p>41-42° C: “41-42° C and such variation above and below as one of ordinary skill in the art would deem appropriate based on the lack of decimal points and the known variability of melting point data to enable identification of solid methylphenidate free base of the invention.”</p>	<p>“The solid begins to liquefy at a temperature between 40.5° C and 41.4° C and becomes liquid throughout at a temperature between 41.5° C and 42.4° C”</p>	<p>“when the solid substance is melted in a capillary melting point apparatus, some liquid is first present at 40.5-41.4° C and the solid becomes liquid throughout at 41.5-42.4° C”</p>

Notwithstanding the differences between the parties’ proposed constructions, there are a few points of agreement regarding the issues involved in the present claim construction. First, there is no dispute that the compound “methyl α -phenyl-2-piperidine acetate free base” in claim 1 discloses methylphenidate free base, and that the further limitation, “in solid form,” requires methylphenidate free base in solid physical form. *See* JM’s Brief at 1; Noven’s Brief at 3; Shire’s Brief at 2-3. Regarding the melting point limitation, the parties agree on the significance of the patent’s disclosure of a melting point using two significant figures without a decimal point. Specifically, the parties agree that a person of ordinary skill in the art would regard such disclosure as incorporating generally accepted principles of rounding, such that numbers ranging from 40.5 to 41.4 would be rounded to 41, and numbers ranging from 41.5 to 42.4 would be rounded to 42 when comparing a measured melting point value to the asserted claims. *See* JM’s Opening Brief at 7; Noven’s Brief at 3; Shire’s Brief at 8. Additionally, there is consensus

among the parties and their respective experts that a number of variables intrinsic to distinct samples of methylphenidate free base in solid form and individual experimental designs will result in varying melting points. For example, JM contends that heating rate, amount of material tested, state of subdivision of the sample, purity, operator error, and instrument variation and calibration can lead to slightly different melting point measurements. *See* JM's Brief at 8. Similarly, Noven asserts that purity, heating rate, calibration, size, and physical forms will affect melting points. *See* Noven Brief at 7-8; Ex. V to JM's Brief at p. 101, l. 16 - p. 102, l. 8, p. 105, ll. 5-22. Finally, Shire suggests that impurities (water, residual solvents, dust, etc.), the stereoisometric composition of a mixture, and workup parameters (drying time, temperature, and variation of solvents) would likewise result in varying melting point measurements. *See* Shire's Brief at 3; Ex. O to JM's Brief at p. 82, l. 20 - p. 83, l. 19, p. 232, l. 4 - p. 233, l. 4. Finally, the parties generally agree that a melting point range, as in these claims, describes the range from the temperature at which the first sign of liquification appears to the temperature at which the material is completely liquefied. *See* JM's Brief at 18; Noven's Brief at 17; Shire's Brief at 7.

The essential point of contention among the parties regarding the disputed phrase, setting aside Shire's proposed instrument limitation, concerns the amount of allowable variation incorporated into the claim limitation and the range of values allowable to affirmatively conclude that the melting point limitation of the '760 patent reads on a measured melting point of an accused product.

JM seeks to define this range as "variation above and below as one of ordinary skill in the art would deem appropriate based on the lack of decimal points and the known variability of melting point data to enable identification of solid methylphenidate free base of the invention." Fundamentally, JM argues that this definition would satisfy the first prong of an infringement

analysis (claim construction), allowing the fact-finder to answer the second prong. JM contends that the jury will determine, after hearing testimony from the various experts, the relevant and applicable variables in evaluating whether the accused product meets the claim limitation.

In support of its proposed construction, JM points to the prosecution history and a number of extrinsic sources. First, JM points to previous published papers of the defendants' experts. In its briefing, JM lists various melting point variations that have been previously accepted by both Noven and Shire's experts in both statements made during deposition and contained within previous scientific publications. *See* Ex. U at 1708; Ex. V at p. 175, ll. 12-25 & p. 177, ll. 8-12; Ex. W; Ex. X at 1206-07; Ex. Y at 557; Ex. Z at 6117-18; and Ex. AA at 1190 to JM's Brief. JM provides these examples to demonstrate the broad range of historically accepted variations by one of ordinary skill in the art. JM also relies on the variability of the tested melting points of the accused product—JM cites to various documents purporting to show the accepted variability among lots of Daytrana™ by Noven. Turning to the prosecution history, JM asserts that the patentee viewed the melting point amendment as “unnecessary for claim 1 to be patentable” and as a way of merely highlighting the uniqueness of the present invention and the erroneous information in the Merck Index. It urges that the examiner's silence regarding the addendum and focus on the discrediting of the Merck Index further supports the assertion that the melting point limitation played no role in patentability. JM also notes that at no time during the prosecution of the '760 patent did the patentee or the examiner discuss limiting the invention to any particular subset of solid methylphenidate free base based on a purity level, crystalline structure, or any other particular property. Accordingly, JM suggests that the function of the melting point limitation is merely a means for identifying and confirming the identity of an

unknown compound, and not to “exclud[e] certain batches of the same compound.” See JM’s Brief at 19-20.

After evaluating the intrinsic and extrinsic evidence, as well as the arguments of the parties, the court is not persuaded by JM’s argument. JM’s argument, at its core, would have the court ignore the claim language and its inclusion of the melting point limitation.²

The Federal Circuit has addressed the importance of numerical claim ranges in claim language. In *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, the court adopted a literal interpretation of a numerical range. 347 F.3d 1355, 1357 (Fed. Cir. 2003). The limitation in question required a “gasoline having a boiling point range of 121° F – 345° F at 1 atmosphere pressure.” *Id.* The court rejected the plaintiff’s reading of the limitation, suggesting that the limitation was only included as a mere method of identification, i.e., “only to confirm the gasoline’s predominant composition.” *Id.* The court also relied on the patentee’s inclusion of the limitation during prosecution for support that the patentee intended a literal interpretation of the claim limitation.³ Again, in *Jeneric/Pentron, Inc. v. Dillon Company, Inc.*, the court adopted a literal interpretation of a numerical range, stating “the claim language indicates that the invention’s chemical components should be limited to the precise ranges set forth therein.” 205

² As a threshold matter, the parties dispute whether the boundaries of the melting point observation—i.e., the observations of liquid for the first time and complete liquification—must occur at a defined range around 41° and 42° C, respectively. Noven and Shire assert that the evidence suggests that the inclusion of two significant factors and the exemplary instrument indicate that the compound must begin to liquefy at 41° C (40.5° C if rounding) and will be completely liquefied at 42° C (42.4° C if rounding). JM, to the contrary, would only require some melting activity to occur at any point within that range. As a matter of claim scope, the court concludes that the onset of melting activity and complete liquification of the compound must occur at a range within 41° and 42° C in order to satisfy the claim limitation. Thus, for example, a product which begins to liquefy at 41.5° C and is completely liquefied at 42° C falls within the scope of the claim. See THE UNITED STATES PHARMACOPEIA, THE NATIONAL FORMULARY 1805 (1995).

³ The court is not persuaded by JM’s argument distinguishing *Talbert* from the present case. In *Talbert*, in support of its analysis, the Federal Circuit acknowledged that the examiner required the precise numerical range limitation for patentability. While such explicit recognition of the limitation was not addressed by the examiner in this case, JM must live within the confines of the language of its asserted claims. See *Ethicon-Endo Surgery*, 93 F.3d at 1583 (noting that, even where the patentee “need not have included [a] limitation in its claim[,] [h]aving done so, it must live with the language it chose.”).

F.3d 1377, 1381 (Fed. Cir. 2000) (internal quotes omitted). The court noted that other numerical limitations in the patent contained broadening words like “about,” whereas, “the precise weight ranges of claim 1 do not avoid a strict numerical boundary to the specified parameter.” *Id.* (internal quotes omitted) (“This construction, assigning numerical precision to composition ranges, is particularly appropriate when other variables in the same claims explicitly use qualifying language.”); *see also Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007) (stating, “[t]his leads to a conclusion that one of ordinary skill in the art would understand the inventors intended a range when they claimed one and something more precise when they did not.”). Much like in *Talbert*, the *Jeneric* court also relied on limiting amendments and statements made during prosecution. *Id.*

Notwithstanding JM’s assertion to the contrary, the claiming of “melting point of 41 – 42° C” is an implicit recognition of the form and purity sought, and it is not simply an indicator of identity.⁴ This is supported by the prosecution history. Prior to the amendment, the patent claimed methylphenidate free base in solid form. The appending of “melting point of 41 – 42° C” to claim 1 reflects an additional distinguishing characteristic of the claimed invention. In addition, the variables cited by the parties, particularly JM, can all be controlled to a certain extent. Indeed, the cited references suggest that those variables and testing parameters should be properly controlled, and instruments should be properly calibrated so as to minimize error.

Additionally, much like in *Jeneric*, the use of a strict numerical boundary in claims 1 and 2 and the inclusion of broadening words in claims 9 and 10 support a literal interpretation of the numerical range. Claims 9 and 10 of the ‘760 patent read as follows:

9. A process for preparing methyl α -phenyl-2-piperidine acetate (free base), which process comprises the steps of:

⁴ In fact, as indicated above, the parties do not dispute the chemical identity at issue in this case.

- (i) stirring methyl α -phenyl-2-piperidine acetate hydrochloride in a suitable organic solvent and aqueous base;
- (ii) evaporating the organic layer to leave an oil which solidifies on standing; and
- (iii) dissolving the crude solid in an organic solvent, cooling to less than 10° C and seeding with crude solid whilst continuing stirring.

10. A process according to claim 9, which process comprises:

- (i) stirring methyl α -phenyl-2-piperidine acetate hydrochloride in heptane and an aqueous inorganic base, such as an alkali or alkaline earth metal hydroxide or carbonate;
- (ii) evaporating the solvent from the organic layer to leave an oil that solidifies on standing; and, optionally,
- (iii) dissolving the crude solid in 2,2,4-trimethylpentane, and seeding with crude solid at below 10° C with stirring. (emphasis added).

Likewise, the specification also contains a reference to an approximation of temperature:

A preferred temperature range for the recrystallisation step (iii) is from about 3° to about 8° C. More preferably, the solution is seeded at from about 8° C to about 10° C and the temperature reduced further to from about 2° to about 5° C during stirring. ‘760 Patent, col. 2, ll. 32 – 36 (emphasis added); *see also id.* at col. 3, ll. 47-50 (describing precise temperatures).

The patentee’s inclusion of words of approximation or variance in some claims and exclusion of them in others, coupled with the patentee’s discussion of approximations in the specification, demonstrates the inventor’s intention to limit “melting point of 41 – 42° C” to its literal range. Consequently, the claim language, specification, prosecution history, and precedent suggest that the court must give literal effect to the melting point limitation.⁵

C. Instrument Limitation

Shire argues that the court should limit the disputed claim term to require measurement of the melting point using a capillary melting point apparatus. Shire argues that one of ordinary skill in the art would read the claim limitation and understand that any measurement of a melting point *range* would require such an apparatus. Shire argues, “unlike other instruments routinely

⁵ In view of this holding, the court need not address the defendants’ argument that JM’s construction renders the claims indefinite.

employed to study solid-liquid phase changes, a capillary melting point apparatus allows one to observe two temperatures. . . .” Shire’s Brief at 7-8. Shire points to the specification, various extrinsic sources, and the inventor’s testimony for support of its instrument limitation.⁶ JM argues that the court should not read the capillary melting point apparatus limitation into the claims.

The specification’s only discussion of melting point discloses as follows:

The combined solids were dried at room temperature in the vacuum over for 15 hours giving methyl-phenyl-2-piperidine acetate (free base) as white solid and their melting point (measured on a Thomas Hoover Capillary Melting Point Apparatus) was found to be 41° - 42°C. ‘760 Patent, col. 3, ll. 58-63 (emphasis added).

Although the issue is close, the case law supports Shire’s argument. In *Honeywell Intern., Inc. v. Int’l Trade Comm’n*, the Federal Circuit considered the construction of the term, “melting point elevation.” 341 F.3d 1332, 1339-40 (Fed. Cir. 2003). The dispute focused on whether the claims required any particular sample preparation method when determining the melting point elevation (“MPE”). Unlike the present case, however, “neither the claims, the written description, nor the prosecution history reference any of the four sample preparation methods that can be used to measure the MPE.” *Id.* at 1339. Accordingly, the Federal Circuit, acknowledging that different sample preparation methods yielded different MPE results, held the claims indefinite as insolubly ambiguous. *Id.* at 1340 (“[T]he claims, the written description, and the prosecution history fail to give us, as the interpreter of the claim term, any guidance as to what one of ordinary skill in the art would interpret the claim to require. Moreover, because the sample preparation method is critical to discerning whether a PET yarn has been produced by the

⁶ The U.S. Pharmacopeia regards the capillary method as the standard technique for melting point determination, as does Vogel’s Textbook of Practical Organic Chemistry. See THE UNITED STATES PHARMACOPEIA, THE NATIONAL FORMULARY 1805 (1995); B.S. Furniss, et al., VOGEL’S TEXTBOOK OF PRACTICAL ORGANIC CHEMISTRY INCLUDING QUALITATIVE ORGANIC ANALYSIS (Longman Scientific & Technical 4th ed. 1987).

claimed process, knowing the proper sample preparation method is necessary to practice the invention.”).

In *ReedHycalog UK, Ltd. v. United Diamond Drilling Servs., Inc.*, Judge Davis applied *Honeywell* and concluded a claim was definite. 2009 WL 1011730 (E.D. Tex. 2009). The claim at issue in *ReedHycalog* required “a thermal characteristic such that a 950 degrees C. temperature at the working surface results in a temperature of less than 750 degrees C. at the depth.” *ReedHycalog*, 2009 WL 1011730 at *8. The defendants argued that the claim language was indefinite for failing to “disclose the conditions, tests, or methods to measure the claimed ‘thermal characteristics.’” *Id.* The court rejected the defendants’ argument. The court concluded that they failed to “show that skilled artisans were aware of multiple methods to measure the claimed thermal characteristics and that the methods produced significantly varied results such that the thermal characteristics cannot be calculated or measured.” *Id.* (citing *Honeywell*, 341 F.3d at 1340-41).

Unlike in *Honeywell* and *ReedHycalog*, the ‘760 patent discloses a specific method to test melting point—a capillary melting point apparatus. Furthermore, in its briefing, Shire suggests that two of the relevant testing methods, capillary melting point apparatus and differential scanning calorimeter (“DSC”), yield different results, and the failure of the court to require an instrument method might render the claims indefinite as DSC and capillary instruments yield different melting points. *See Honeywell*, 341 F.3d at 1340; *ReedHycalog*, 2009 WL 1011730 at *8.

Under *Honeywell*, Shire’s argument is persuasive. The claim’s disclosure of a melting point range, coupled with the specification’s suggestion of a measuring instrument, support Shire’s argument. When the court adds to those facts the understanding that the industry

standard instrument for measuring melting point range is a capillary melting point apparatus, the court concludes that Shire's argument has merit.

For all of the foregoing reasons, the court defines "having a melting point of 41 – 42° C" as follows: **"the solid begins to liquefy and becomes liquid throughout at a temperature range between 40.5° C and 42.4° C, as measured by a capillary melting point apparatus."**

IV. Conclusion

The court adopts the above definitions for those terms in need of construction. The parties are ordered that they may not refer, directly or indirectly, to each other's claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the court.

SIGNED this 21st day of July, 2009.


CHARLES EVERINGHAM IV
UNITED STATES MAGISTRATE JUDGE